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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

LISA TREMAINE, Plaintiff, v. MEDTRONIC, INC., a Minnesota Corporation, DOES I-X and ROE CORPORATIONS I-X, inclusive, Defendants.	Case No. 2:06-CV-737-LDG-LRL **MEDTRONIC, INC'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT REGARDING PLAINTIFF'S LACK OF EVIDENCE OF DEFECT AND CAUSATION** **[Concurrently Filed With Declaration Of Ginger Pigott; Request For Judicial Notice]**

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I.
INTRODUCTION

All of plaintiff's claims still suffer from the same fatal flaw: there is no evidence to support plaintiff's contention that Medtronic's product – the Synergy Versitrel System, which included the Specify Lead as a component – was defective, or that a defect was the cause of plaintiff's injury.

Plaintiff's theory depends on her supposition that the Specify Lead component was too thick for safe implantation in the cervical area of her spine, and that Medtronic failed to warn of the risk of paralysis she says was the result. But plaintiff does not dispute critical evidence, and this failure to do so means that no genuine, triable issue of material fact exists regarding the essential elements of defect and causation. For example, plaintiff does not dispute that the Specify Lead has been (and continues to be) safely used in many patients in the cervical spine without adverse outcome, or that implantation of any device anywhere in the spine can lead to paralysis even in the absence of product defect or medical negligence.

Similarly, she cannot (and does not) dispute that the risk of paralysis is well known in the medical community and warned about in Medtronic's written material. Plaintiff also cannot dispute that her surgeon specifically warned her of the risk of paralysis. Instead, she claims that the paralysis warning for the Specify Lead was not adequate to advise her surgeon of some "increased risk" of paralysis when used cervically.

This theory, however, is fundamentally flawed. Plaintiff has no competent evidence, including any of the required expert evidence, that use of a Specify 3998 lead in the cervical spine actually creates an increased risk of paralysis, or that the lead has a defect because it is not appropriate for use in the cervical spine. Without this, all of plaintiff's claims, which are premised on the theory that Medtronic knew of and failed to warn of this alleged defect, fail as a matter of law.

First, plaintiff has not adduced any competent admissible evidence demonstrating that the thickness of the Specify Lead or the absence of warnings about implanting it in the cervical spine causes an increased risk of paralysis. Plaintiff merely advances a fallacy,

unsupported by law, that a "lead which causes paralysis is a defective product." *Pl.'s Opp. Mot. Summ. J. re No Evidence of Defect and Causation*, [Doc. 87] ("*Pl.'s Opp.*"), p. 4. Nevada law carefully defines what makes a product "defective." For a state-of-the-art medical device like the one implanted in plaintiff, admissible expert evidence must first establish the existence of a defect in the product and then establish the causal link between that alleged defect and the injury that occurred. Here, none of the medical experts in this case opine that the Specify Lead was inappropriate for use in the cervical spine or that the labeling was defective, and none link up any supposed defect to the cause of her injuries.

Second, plaintiff's entire theory of defect rests on one patent application for a lead that the inventors themselves stated was just an idea developed to explore the possibility of creating a thinner lead as another tool for treating patients. Both patent inventors have testified that neither viewed the patent application as an indictment of existing technology or a suggestion that the leads on the market were somehow "defective." Advances in medical technology would come to a screeching halt if existing products were deemed "defective" simply because of efforts to develop improved alternatives. Plaintiff's only other evidence is equally incompetent and insufficient: Dr. Thalgott's statement about preferring to use other leads in the cervical spine was purportedly made after plaintiff's surgery and is thus irrelevant and inadmissible. (Decl. of Ginger Pigott In Support of Medtronic's Motion for Summary Judgment Re Lack of Evidence of Defect and Causation [Doc. 78], (hereinafter "Doc. 78", Ex. V, Thalgott Depo., 34:2-10; 44:21-24)). Dr. Thalgott also has admitted under oath that he had repeatedly perjured himself on other occasions; therefore, his testimony is without any credibility whatsoever.

Third, the warnings for the Specify Lead, as conveyed and understood by plaintiff's implanting surgeon, were proper, appropriate, and reviewed by the FDA – and adequate as a matter of law.

Finally, both the implied and express warranty claims fail because quite simply, plaintiff cannot state a valid claim for any breach of implied or express warranty, much less controvert the undisputed material facts with any evidence.

Because there is no material issue of fact genuinely in dispute, Medtronic's motion for summary judgment regarding plaintiff's lack of evidence of defect and causation must be granted in its entirety.

II.
PLAINTIFF HAS NOT RAISED ANY GENUINE ISSUE OF MATERIAL FACT REGARDING DEFECT OR CAUSATION

In accordance with Local Rule 56-1, Medtronic offered a series of undisputed material facts demonstrating that the Specify Lead was not defective in its moving papers. Plaintiff has not carried her burden of controverting these undisputed facts in her Opposition, and for the Court's ease of reference, they are summarized here:

Plaintiff Has Failed to Raise Any Fact Issues Regarding Defect or Causation	
Undisputed Fact	***Evidence***
There is no evidence of defect since paralysis can occur in the absence of defect and there is no evidence that the Specify Lead was inappropriate for use in the cervical spine.	**Undisputed; *neither* of plaintiff's medical experts had an opinion about whether the Specify Lead was inappropriate for the cervical space of the spinal cord.** o Doc. 78, Ex. Q, Azrieli Depo., 62:15-18; 92:3-14) (no opinion as to the appropriateness of the Specify Lead in the cervical space of the spinal cord). o Doc. 78, Ex. R, Farrow Depo., 38:12-22 (no opinion as to the exact mechanism of plaintiff's injury, including appropriateness of the Specify Lead).
No scientific or medical literature offered to show any defect in lead or any increased risk of paralysis when used in the cervical spine.	**Undisputed; experts do not provide any scientific or medical literature that demonstrates that the size of a lead is a defect or relates to an increased risk of paralysis.** o Doc. 78, Ex. Q, Azrieli Depo., 78:22-79:5) (no medical literature has been reviewed to determine whether the size of the lead can cause compression of the spine). o Doc. 78, Ex. Q, Azrieli Depo., 98:9-25 (no medical literature has been reviewed that discusses the potential of objects placed in the cervical spine as causing compression of the spinal cord). o Doc. 78, Ex. AA, Henderson Depo., 74:10-14 (not aware of any peer-

	reviewed literature that is critical of the use of any existing surgical paddle leads versus the Specify Lead for use in the cervical spine).
No expert has said that an alternative lead (such as the one described in the patent application if such a lead could be manufactured, which has not proved feasible) would have prevented plaintiff's paralysis injury.	**Undisputed; *neither* of plaintiff's experts opined to any degree of certainty that a smaller lead would have prevented plaintiff's injury.** o Doc. 78, Ex. Q, Azrieli Depo., 102:6-16 (opining that he is not an expert and could not answer whether the implanting of anything in the spinal cord could not lead to an injury). o Doc. 78, Ex. R, Farrow Depo., 47:9-23 (opining only that putting anything into the spinal cord is dangerous and that a thinner lead is a good idea).
Subsequent to plaintiff's surgery, plaintiff's implanting surgeon had no criticism of the Specify Lead and continues to use the Specify Lead in the cervical spine of his patients.	**Undisputed; plaintiff's surgeon has no criticisms of the Specify Lead that was implanted into plaintiff, and has continued to use the Specify Lead subsequent to plaintiff's surgery.** o Doc. 78, Ex. A, Garber Depo., 38:8-10 (implanting surgeon testifying under oath that he has no criticisms of the Specify Lead that was implanted into plaintiff). o Doc. 78, Ex. A, Garber Depo., 100:13-15 (implanting surgeon testifying under oath that subsequent to plaintiff's surgery, he has implanted the Specify Lead in the cervical spine an estimated five or so times).
After plaintiff's surgery, Dr. Thalgott purportedly told Medtronic representative that he preferred using another lead over the Specify Lead for cervical spinal surgery. However, he indicated that he had no criticism of Dr. Garber's use of the Specify Lead in plaintiff's surgery.	**Undisputed; Dr. Thalgott's statement of preference was made *after* plaintiff's surgery so it is not relevant. Dr. Thalgott himself has no criticism of the use of the lead in plaintiff.** o Doc. 78, Ex. V, Thalgott Depo., 14:18-15:5 (noting his preference of using the resume lead over the Specify Lead). o Doc. 78, Ex. P, Ruther Depo., 203:2-8 (opining that the timing of Dr. Thalgott's opinion does not have any relevance to Medtronic's duty to warn). o Doc. 78, Ex. V, Thalgott Depo., 44:21-24 (noting no criticism of Dr. Garber or his choice of the Specify Lead).

Plaintiff Has Failed to Raise Any Fact Issues Regarding the Adequacy of the Paralysis Warning	
Undisputed Fact	***Evidence***
The Specify Lead's labeling warns about the risks of paralysis associated with its use.	**Undisputed; the labeling for the Specify Lead specifically warns about the risks of paralysis.** o Declaration of Ginger Pigott in Support of Defendant Medtronic's Memorandum of Law Re Preemption, Doc. 61 (hereinafter "Doc. 61"), Ex. B, Specify Model 3998 Lead Kit, MDT00976 (naming paralysis as possible adverse event).
The risks of paralysis in spinal cord surgery are known to the medical community, and were known to plaintiff's surgeon (Dr. Garber) in particular.	**Undisputed; plaintiff's implanting surgeon and plaintiff's expert agree that paralysis is a generally known risk of spinal cord surgery.** o Doc. 78, Ex. A, Garber Depo., 4:17-7:8 (implanting surgeon testifying under oath that paralysis is a generally known risk of spinal cord surgery). o Doc. 78, Ex. P, Ruther Depo., 209:23-25 (expert agreeing that paralysis is a risk for all spinal cord surgeries).
Peer-reviewed literature indicates that there is a "very small amount of difference [in existing space] between those two regions [the thoracic and cervical regions] of the spine" and that in terms of room for proper lead placement, the upper cervical spinal section is "largest of any place in the cervical spine," and there is a "huge amount of space in the upper most part of the cervical spine."	**Undisputed; plaintiff's expert could not testify as to the neuroanatomy of the spinal cord because he was not an expert. Defendant's expert's testimony on this point –that the upper cervical spinal section is the *largest* of any place in the cervical spine – thus is undisputed.** o Doc. 78, Ex. Q, Azrieli Depo., 86:21-87:7 (confessing to not know the neuroanatomy of the spinal cord to opine about its relative spacing). o Doc. 78, Ex. AA, Henderson Depo., 80:3-4; 77:21-78:5 (outlining that from peer-reviewed literature, there is a small difference between the thoracic and cervical regions of the spinal cord, but that in terms of proper lead placement, the upper cervical spinal section is the largest).
Physicians, including neurosurgeons, must exercise their own independent medical judgment when deciding to implant the	**Undisputed; physicians must use their independent medical judgment when implanting the Specify Lead.**

Specify Lead, and as the implanting surgeon testified, if Dr. Garber determined intraoperatively that the Specify was too large for the cervical space, he would not have implanted the lead.	o Doc. 78, Ex. AA, Henderson Depo., 63:5-21 (physicians must use their independent medical judgment). o Doc. 78, Ex. A, Garber Depo., 144: 18-145:12 (implanting surgeon agreeing that he would not have implanted the Specify Lead if he determined it was too large for plaintiff's cervical spine).
The Specify Lead was appropriate for the cervical spine.	**Undisputed; plaintiff's experts fail to render an opinion that the Specify Lead was defective or even inappropriate for the cervical spine.** o Doc. 78, Ex. Q, Azrieli Depo., 62:15-18; 92:3-14) (no opinion as to the appropriateness of the Specify Lead in the cervical space of the spinal cord). o Doc. 78, Ex. R, Farrow Depo., 38:12-22 (no opinion as to the exact mechanism of plaintiff's injury, including appropriateness of the Specify Lead).
Plaintiff was personally warned about the risks of paralysis.	**Undisputed; plaintiff consented to the operation and was informed of all risks, including paralysis, associated with the surgery.** o Doc. 78, Ex. M, Consent to Operation, signed March 17, 2004.
Subsequent to plaintiff's surgery, plaintiff's implanting surgeon has had no criticism of the Specify Lead, and he continues to use the Specify Lead in the cervical spine of his patients.	**Undisputed; plaintiff's surgeon has no criticisms of the Specify Lead that was implanted into plaintiff, and has continued to use the Specify Lead subsequent to plaintiff's surgery.** o Doc. 78, Ex. A, Garber Depo., 38:8-10 (implanting surgeon testifying under oath that he has no criticisms of the Specify Lead that was implanted into plaintiff). o Doc. 78, Ex. A, Garber Depo., 100:13-15 (implanting surgeon testifying under oath that subsequent to plaintiff's surgery, he has implanted the Specify Lead in the cervical spine an estimated five or so times).
Plaintiff's Manufacturing and Design Claims Does Not Survive Summary Judgment	
Undisputed Fact	***Evidence***
Plaintiff has abandoned her manufacturing and design defect product liability theories.	**Undisputed.** o Doc. 90, Ex. KK, Plaintiff's Third

	Supplemental Answers to Defendant's First Set of Interrogatories (stating that it is not plaintiff's contention that the "Specify 3998 Lead at issue in this case was mis-manufactured or had a manufacturing defect"). o Doc. 78, Ex. P, Ruther Depo., 108:13-109:4) (expert confirming that she received no information or direction from plaintiff's counsel regarding these causes of action).
Plaintiff's Breach of Warranty Claims Does Not Survive Summary Judgment	
Undisputed Fact	***Evidence***
Plaintiff was provided and consented to the risks of paralysis.	**Undisputed; plaintiff consented to the operation and was informed of all risks, including paralysis, associated with the surgery.** o Doc. 78, Ex. M, Consent to Operation, signed March 17, 2004.
Plaintiff relied on her physicians to select the Specify Lead and Synergy Verstirel System.	**Undisputed**. o Doc. 78, Ex. X, Tremaine Depo., 97:20-24 (relied on Dr. Garber to know of plaintiff's condition and select appropriate medical devices).

Plaintiff has offered no competent and reliable evidence demonstrating that as a matter of law, these facts can be disputed. Therefore, her claims cannot survive summary judgment.

III.
LEGAL ARGUMENT

Plaintiff's Opposition fails to set forth any genuine issues of material fact as Rule 56(c) requires. Plaintiff argues through a variety of unsupported factual scenarios and poses several speculative questions, but she fails to come forth with relevant, admissible evidence demonstrating that she could carry her *prima facie* burden of proof at trial for essential elements of her claim. Instead, it is clear that at this juncture – with discovery now closed – there is simply no evidence supporting plaintiff's case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). A complete failure of proof concerning the essential elements of the plaintiff's claims necessarily renders all other facts immaterial. *Id.*, at 323.

A. Plaintiff's Claims All Fail Because There Is No Admissible Evidence To Establish Plaintiff's Claims That The Lead Is Defective, That The Lead Is Capable Of Causing An Increased Risk of Paralysis, Or That The Lead Actually Caused Paralysis In This Case

Plaintiff asserts that "[a] lead which causes paralysis is a defective product." *Pl.'s Opp.*, p. 4. This assertion demonstrates the fundamental problem with plaintiff's theory. Not only is there no authority to support such a bald, *ipse dixit* proposition, but there is no evidence either.

As an initial matter, even if plaintiff were still pursuing a design defect claim, Comment k to the Restatement (Second) of Torts provides that strict liability cannot be imposed on unavoidably unsafe products that are properly prepared and accompanied by proper warnings. The Nevada Supreme Court has stated that comment k would be in "harmony with [its] cases" if the principle was read to mean that strict liability cannot attach where the dangers are properly conveyed to the individual and the individual accepts that risk. *Allison v. Merck*, 110 Nev. 762, 773 (1994) (rejecting the application of comment k where the consumers have no choice but to use the unavoidably unsafe drug) (plurality opinion). Here, however, there is no factual dispute that the proper warnings about the possibility of paralysis were conveyed to plaintiff's physicians, and to plaintiff herself, and that they both decided to proceed.

Moreover, plaintiff's sole unwaived product liability theory is failure to warn – in other words, that there was a warning defect that caused her injuries. In the context of a prescription drug or device, an "adequate warning" is one that would accurately inform the reasonably prudent physician of the risks involved in using the product. *See Harris v. Belton*, 65 Cal. Rptr. 808, 816 (Cal. App. 1969); 21 CFR § 801.109 (prescription devices are those that are not safe except under the supervision of a practitioner licensed by law to direct the use of such device). Therefore, where a warning cautions of the exact harm that occurs, the warning should be deemed adequate by the court as a matter of law. *Temple v. Velcro USA, Inc.*, 196 Cal. Rptr. 531, 533 (1983). In light of this standard, it is never enough for plaintiff to simply posit the existence of a defect. In addition, it is never enough for plaintiff

to posit a casual connection between the hypothetical defect and an injury – she must have competent, sufficient scientific and medical evidence on the point. *See Morin v. U.S.*, 535 F. Supp. 2d 1179, 1185 (D. Nev. 2005) (requiring that issues of causation be resolved through scientifically reliable evidence, including through qualified expert witness testimony); *Price v. Blaine Kern Artista, Inc.*, 893 P.2d 367, 370 (Nev. 1995) (causation is established where the plaintiff can demonstrate that a "defect in the product was a substantial factor in causing [her] injury"). Plaintiff, however, has not come forward with any evidence demonstrating a defect in the lead, or how her claimed defect caused her injury.

1. Plaintiff Fails To Carry Her Prima Facie Burden Of Establishing The Existence of a Defect

Nevada's requirement for establishing the existence of a defect contrasts with plaintiff's bald statement: that a lead is defective if it causes paralysis. This is not evidence, it is assumption. So, what is the defect? As detailed in the charts above, plaintiff fails to come forward with competent evidence demonstrating that there was a defect.

Moreover, neither Drs. Azrieli nor Farrow – plaintiffs' only medical experts – suggest that the size of the lead was itself a defect and neither offers an opinion as to the inadequacy of the warnings given. *See supra*, pp. 5-7. Again, what is the defect? Plaintiff has no evidence to say.

2. Plaintiff Fails To Carry Her Prima Facie Burden Of Establishing Causation

Whereas causation demands that the "***defect in the product*** was a ***substantial factor*** in causing [her] injury," the most plaintiffs' experts will say is that they believe the lead played some undefined role in her injury. *Price v. Blaine Kern Artista, Inc.*, 893 P.2d 367, 370 (Nev. 1995) (emphasis added). This does not raise a triable issue of fact on causation

To begin with, both of plaintiff's experts conclude that the Specify Lead might be causally connected to plaintiff's injuries, but fail to offer any evidence – from literature, case reports, or any other source independent from this litigation – supporting the general possibility that the placement of a particular lead can cause a paralysis injury in a patient

because of the lead's ***size***. (Doc. 78, Ex. Q, Azrieli Depo., 98:3-99:19). Even more telling was the lack of any testimony that a ***defect*** caused plaintiff's injury.

Dr. Azrieli said the lead was implicated in plaintiff's injury based on (1) the testimony of the implanting surgeon, Dr. Garber, who claimed that the patient was able to move her limbs immediately after surgery, which Dr. Azrieli believed meant that the injury did not occur during the surgery itself [*id.*, 64:8-12]; and (2) the testimony of Dr. Thalgott, who allegedly said after plaintiff's surgery that he prefers using other leads over the Specify Lead for cervical spinal surgery [*id.*, 61:14-62:14].

However, Dr. Azrieli did not opine that it was the size of the Specify Lead and/or a defect or its inappropriateness for the cervical spine that caused plaintiff's injury. He said the dimensions of the Specify Lead were "[s]omewhat" important to his opinion, but did not opine as to the appropriateness of the Specify Lead in its placement of cervical spine, or whether there were any design, manufacturing or labeling inadequacies with the Specify Lead. (*Id.*, 62:19-64:11). He also could not form an opinion about whether there was in fact less space in the cervical spine versus other areas of the spine because he admitted to not having any expertise in neuroanatomy. (*Id.*, 87:10-25; 94:9-17).

Dr. Azrieli also disavowed any expertise in the surgical aspects of implanting leads such as the Specify Lead. (*Id.*, 32:20-24). As a result, he never bothered to even rule in the very cause that plaintiff argues for her case: that the Specify Lead was inappropriate for placement in plaintiff's cervical spine because of its size. For example:

> Q. Are you going to be offering any opinions in this case as to whether or not it was appropriate to utilize the Specify 3998 in the cervical spine?
> **A. Not at all, no.**
> * * * *
> Q. And then did you have any opinion one way or the other with regard to Dr. Henderson's opinion that this particular Specify 3998 lead was appropriate for use in the cervical spine in the right patients? Did you have an opinion one way or another?

9 A. No.

(Doc. 78, Ex. Q, Azrieli Depo., 62:15-18; 92:3-9) (emphasis added).

Therefore, Dr. Azrieli's testimony fails to provide the causal link for all of plaintiff's claims: that the inappropriate size of the Specify Lead for the cervical spine and Medtronic's failure to warn of this increased risk caused plaintiff's injury.

Dr. Farrow, on the other hand, did not even form an opinion on what caused plaintiff's injury, much less conduct differential diagnosis, so his testimony is completely irrrelevant.

12 Q Did you offer any opinion as to whether any of
13 these possible mechanisms were more likely than not the
14 cause in Lisa Tremaine's case?
15 A I don't think so.
16 **Q Have you, as you sit here today, have you**
17 **formed an opinion as to the exact mechanism of Lisa**
18 **Tremaine's injury?**
19 **A No.**
20 Q Have you been able to rule out any of the
21 possible mechanisms that you've identified?
22 A No.

(Doc. 78, Ex. R, Farrow Depo., 38:12-22) (emphasis added).

Dr. Farrow's consultation note written shortly after treating plaintiff, stated: "Alas, I think that the patient has a post traumatic myelopathy related to the implantation of the stimulator wires. I have seen this before." (*Pl.'s Opp.*, Ex. 18, Farrow Consultation). This, plaintiff claims, is dispositive of the conclusion that the Specify Lead caused plaintiff's injury. *Pl.'s Opp.*, p. 22. But, Dr. Farrow explained that he wrote this note because during a previous experience, he had seen a patient who also had a cervical cord stimulator implanted, and was found to be weak or partially paralyzed in the recovery room. (Doc. 78, Ex. R, Farrow Depo., 16:14-20). He states that his "recollection" of this opinion was that "it seemed quite likely that the trouble was in some way related to the insertion of the device." (*Id.*, 14:22-24). These statements say ***nothing*** about the Specify Lead, and more importantly, does not support the conclusion that the Specify Lead's size caused the injury.

3. Plaintiff's Experts Do Not Conduct Differential Diagnosis For Their Causation Analysis

Perhaps recognizing that her experts are not actually offering the opinion she needs to survive summary judgment (that the Specify Lead was an inappropriate sized lead for the cervical spine or that Medtronic's failure to warn of this caused her injury), plaintiff now claims a "differential diagnosis" offered by Drs. Azrieli and Farrow sufficiently proves causation. Plaintiff claims that these doctors eliminated some possibilities of causal connections over others, and that their cursory analysis was sufficient. It is not.

Differential diagnosis is defined as "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings." *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003). The "first step in the diagnostic process" is to compile a set of "generally capable" competing causes. *Id.* at 1058. The court in *Clausen* cautioned that the suspected different causes must "actually be capable of causing the injury; or, in other words, the suspected cause must be ***generally*** capable of causing the patient's symptoms. *Id.* The ***second*** step in the differential diagnosis requires that after ruling in all general potential cause, the doctor must eliminate each, one by one to reach a conclusion about the cause specifically applicable to the plaintiff's case. *Id.*

Plaintiff's interpretation of this standard is faulty because she does not link any alleged defect to the injury. As Dr. McNulty, one of plaintiff's physicians testified, one of the potential causes for plaintiff's injury could stem from the surgical procedure itself. (Doc. 78, Ex. G, McNulty Depo., 88:1-11) (testifying that if a lead is inserted at too steep an angle to the spine, the surgeon may exert too much pressure on the spinal cord, causing undue trauma). Not only did Drs. Azrieli and Farrow fail to actually rule in the possibility of injury due to the Specify Lead's size as plaintiff hypothesize, but the doctors also ruled out the possibility of possible surgical or insertional error of the lead, without the appropriate qualifications to do so. (Doc. 78, Ex. R, Farrow Depo., 37:24-39:16) (providing three possible scenarios for plaintiff's injury that *assumes* no surgical error). As extensively

provided in the concurrently filed Medtronic Inc.'s Motion to Exclude Plaintiff's Experts [Doc. 76], plaintiff's experts are unqualified to rule out the possibility of a surgical mishap, or malpractice, committed during the course of the surgery itself. Both of plaintiff's experts are neurologists, not neurosurgeons, and are unqualified to opine about the possible causes of a spinal cord injury that occurred during a spinal cord surgery. *See Kozak v. Medtronic, Inc.*, 512 F. Supp. 2d 913, 918 (S.D. Tex. 2007) (expertise in one field is not sufficient to create expertise in another fields). In medical malpractice cases, for example, the courts have held that neurologists are not qualified to testify about the standard of care applicable for surgeons performing spinal surgeries, and the neurologists are not qualified to testify "as to the breach of the standard of care or proximate causation." *Lloyd v. Kime*, 654 S.E.2d 563, 567 (Va. 2008). It would therefore be illogical for either doctor to opine as to the cause of plaintiff's injury, much less rule out the possibility of surgical error with any degree of confidence.

Plaintiff's burden here was to demonstrate that as a general matter, the Specify Lead – due to its size – carries a heightened risk of paralysis associated with its placement in the cervical spine, ***and***, through differential diagnosis, demonstrate that the Specify Lead's heightened risk of paralysis caused this plaintiff's injury. No such evidence has been set forth here. Therefore, none of her claims can survive summary judgment as a matter of law.

B. Plaintiff's Failure To Warn Claim Does Not Survive Summary Judgment

Plaintiff's failure to warn claim turns on whether she can demonstrate that there is a need for a paralysis warning different from the one that was given. Plaintiff does not provide any competent evidence demonstrating this to be the case. First, there is no competent evidence that the size of the Specify Lead merits a warning about some heightened risk of paralysis. Second, the paralysis warnings and labeling accompanying the Specify Lead were sufficient as a matter of law. Finally, the learned intermediary doctrine breaks the causal connection between any alleged defect and Medtronic, for plaintiff's own surgeon has continued to use the Specify Lead in the cervical region on subsequent patients after plaintiff's injury and just as important, plaintiff consented to the very risks of paralysis linked to spinal cord surgery that materialized here.

1. Plaintiff Has Failed To Proffer Any Verifiable, Relevant Scientific Evidence Demonstrating That A Heightened Warning About Placing The Specify Lead In The Cervical Spine Was Warranted

Plaintiff repeatedly claims that there was a "specific risk of paralysis caused from use of unsuitable lead" that is "easily distinguishable from general risks associated with surgery in the spinal cord area." *Pl.'s Opp.*, p. 24. In support of these allegations, plaintiff references the patent application language and Dr. Thalgott's comment. *Id.*, pp. 25-28. As a matter of law, however, these two pieces of evidence are simply insufficient to establish that some warning was necessary and plaintiff cites to no authority demonstrating the sufficiency of this evidence.

First, the FDA prohibits warnings that are without valid scientific foundation. 21 C.F.R. 860.7 (by federal regulation, when the FDA reviews the safety and effectiveness of a device, the agency relies upon only ***valid scientific evidence*** to determine whether there is reasonable assurance that the device is safe and effective). Under no circumstances would statements in an unrelated patent application and one doctor's comment meet the FDA's standard and allow for inclusion of this asserted warning. Second, as an evidentiary matter, these two pieces of evidence are not competent. *See Glastetter v. Novartis Pharm's. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (noting that company's internal documents and their out-of-context statements about causation are not reliable evidence for experts to consider in causation analysis). *See Def.'s Memo. To Exclude Plaintiff's Experts* [Doc. 76], pp. 15-17.

a. The Patent Application

With respect to the patent application that plaintiff argues supports the conclusion that the Specify Lead and other currently existing leads are inappropriate for the cervical spine, the most recent deposition testimony of Tom Cross,[1] one of the two named patent inventors,

[1] On April 30, 2008, after Medtronic filed its Motion for Summary Judgment regarding plaintiff's lack of evidence of defect and causation, plaintiff served a 30(b)(6) notice relating to the patent application publication. (Declaration of Ginger Pigott In Support of Reply For Motion for Summary Judgment re No Evidence of Defect and Causation, Ex. MM, Notice of Taking Deposition). Medtronic objected to the Notice, arguing that the Notice was overly broad, burdensome and cumulative to previous testimony already provided by Tom Cross and Gabor Racz. However, Medtronic designated Tom Cross for deposition, and plaintiff took Cross' deposition on May 13, 2008.

places the language of the patent in its proper context. As the designated Rule 30(b)(6) witness for Medtronic, Cross explained that the idea for creating a smaller lead was initiated by his co-inventor Dr. Gabor Racz, a non-Medtronic consultant. (Decl. of Ginger Pigott In Support of Reply For Motion for Summary Judgment re No Evidence of Defect and Causation, Ex. LL, Cross Depo., 10:5-20). According to Cross, Dr. Racz wanted to work on a "new tool, some sort of an innovation, something that was new compared to other things." (*Id.*, 12:4-10). This was not motivated by any concerns in the community or within Medtronic, but rather was part of Medtronic's work with its customers to explore new ideas and therapies. (*Id.*, 12:1-10; 14:20-15:3; 43:23-44:11).

Further, with respect to the size of this lead imagined in the patent application, Cross testified that he was the individual who decided that "0.030 inches" would be the thickness he was proposing for the new lead because it was simply the thinnest he could possibly create in the lab. (*Id.*, 18:3-12). The significance was simply the mathematics of the material in conjunction with trying to turn Dr. Racz's new concept into a laboratory model.

And, important for discussions here, the language in the patent application to which plaintiff cites – paragraph 10 of the background section – is described by Cross as intended to reflect that in order to achieve the thinness being outlined in the new idea, existing silicone would not be suitable so he had to consider other materials in order to achieve the desired outcome. (*Id.*, 42:7-43:18). Cross testified that he was aware of no information within Medtronic to support a conclusion that Medtronic believed or had reason to believe that existing leads were not suitable for use as labeled. (*Id.*, 40:12-41:5).

This testimony, is entirely consistent with the testimony by Dr. Racz: that the patent application was dictated by the formalities required in patent applications in order to try to illustrate patentability, and was not meant as an indictment on the currently existing technology -- and that even today, Dr. Racz himself recommends the Specify Lead "virtually exclusively" for cervical use. (Doc 78, Ex. W, Racz Depo., 83:5-6). Plaintiff has no testimony to counter it, and her counsel's hypotheses otherwise are not evidence. The patent

application therefore does not create a triable issue of fact regarding whether there was some higher risk associated with the device, or that Medtronic knew about this risk.

b. Dr. Thalgott's Alleged Preference Statement Following Plaintiff's Surgery

Plaintiff continues to argue that Medtronic ignored a "complaint" by Dr. Thalgott regarding placement of the Specify Lead's in the cervical spine. But it bears repeating, even though plaintiff ignores this fact, that Dr. Thalgott merely stated his preference of leads for use in the cervical spine, ***after*** plaintiff's surgery. This alone renders Dr. Thalgott's alleged comment irrelevant on the very issue plaintiff offers it: what Medtronic knew at the time plaintiff was implanted with its medical device.

The substance of this statement also demonstrates that it is hardly the kind of credible, well-supported scientific opinion rising to the requisite level of certainty. Although plaintiff glosses over the particulars, as Dr. Thalgott testified, his memory of his comment to Medtronic's sales representative, Petroni, was as follows:

> What I asked him, to my memory is: Did he put a cervical resume in? And he said – meaning Dr. Garber – he said, No. I said, Did he put a standard lead in? Meaning a noncervical or a thoracic lead. And he said, Yes. I said, Well, I don't use those. I only use cervical resume leads.

(Doc. 78, Ex. V, Thalgott Depo., 14:22-15:5).

These comments simply do not rise to the level of competent evidence that the Specify Lead itself was inappropriate in size for the cervical spine. If this were true, then one doctor's comment about what he prefers to use in his own patients could be held as the standard of care for all other doctors. This defies logic, and further, is not sufficient evidence to survive summary judgment.

Dr. Thalgott, moreover, has ***admitted to numerous instances of perjury*** in connection with a criminal conspiracy prosecution that has received substantial recent publicity. *See* concurrently filed *Request for Judicial Notice*. Dr. Thalgott's testimony thus does not even deserve admission.

2. The Specify Lead's Paralysis Warnings Were Sufficient As A Matter Of Law

As noted, plaintiff claims that the Specify Lead's warnings were insufficient because they did not warn that the lead's size is inappropriate for the cervical spine but failed to develop what, if any, evidence demonstrated that the danger associated with the Specify Lead's ***size*** was in fact substantiated. No duty to warn is triggered where a particular danger is not anticipated. *Yamaha Motor Co., USA v. Arnoult*, 955 P.2d 661, 665 (Nev. 1998) (holding that a duty to warn is triggered only where there is reason to anticipate that a danger may result from a particular use of a product); *Nev. Power Co. v. Monsanto Co.*, 955 F.2d 1304, 1308 (9th Cir. 1992) (applying Nevada law and holding that liability for failure to warn cannot arise when the manufacturer did not reasonably know of the hazard).

Thus, as a matter of law, Medtronic satisfied its duty to warn because it did specifically warn about the possibility of paralysis in all of its warnings accompanying the use and implantation of the Specify Lead. (Doc. 61, Ex. B, Specify Model 3998 Lead Kit, MDT00976) (naming paralysis as a potential adverse event)).

The warning also was adequate as a matter of law because it was required, reviewed and approved by the FDA when the Specify Lead was initially cleared as a 510(k) device in 1998, and further reviewed when the FDA reviewed and approved of all the labeling for the spinal cord stimulation devices in 2001. (Doc. 78, Ex. S, Specify Lead 410(k) Clearance Letter; Doc. 78, Ex. T, July 18, 2003 Labeling Architecture, MDT3592). In particular, when the FDA approved of the PMA supplement that sought to modify the labeling for all leads, among other components, the FDA did not require any changes to statements about the location of the lead placement or warnings regarding paralysis for the Synergy Versitrel System or the Specify Lead. (Doc. 61, Ex. R (P840001/S69 FDA approval letter for the Labeling Architecture, MDT3606-MDT3614)).

3. Plaintiff Cannot Dispute That Her Surgeon, the Learned Intermediary, Knew Of The Paralysis Risks Associated With Using The Specify Lead, And Continued To Use The Specify Lead In The Cervical Spine After Plaintiff's Surgery

Under the learned intermediary doctrine, Medtronic has no liability since the learned intermediary in this case was aware of all paralysis risks associated with implanting the Specify Lead in the cervical spine.

As made evident in *Reyes v. Parke-Davis & Co.*, 498 F.2d 1264, 1276 (5th Cir. 1974), "[p]rescription [products] are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." The manufacturer therefore discharges of its duty to warn the patient, when it warns the expert – i.e., the prescribing physician – of all known or knowable risks.

The causal connection between the manufacturer's alleged failure to warn and the learned intermediary is further broken where plaintiff cannot demonstrate that stronger warnings would have altered the surgeon's conduct. *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (claim based on insufficient warnings cannot survive summary judgment where stronger warnings would not have altered the conduct of the prescribing physician). A mere statement that the doctor would heed, or consider, the warning is insufficient; the plaintiff must show that a proper warning ***would have changed the decision of the treating physician***. *Ackermann v. Wyeth Pharms.*, --- F.3d --- , 2008 WL 1821379 (5th Cir. April 24, 2008); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (heeding a warning "'means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus"). Here, while Dr. Garber said that he would have "heeded" a warning about the Specify Lead's appropriateness for the cervical spine, the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed Dr. Garber's decision to implant the Specify Lead and the

Synergy Versitrel System into this plaintiff. (Doc. 78, Ex. A, Garber Depo., 142:6-15); *Odom*, 979 F.2d at 1003 (citing *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812-14 (5th Cir. 1992)).

Here, the undisputed material facts are as follows: (1) Dr. Garber was provided with all of the FDA-approved warnings related to the use of the Specify lead, including warnings about the possibility of paralysis; (2) Dr. Garber possessed independent knowledge of the risks associated with any spinal cord surgery, including that of paralysis; (3) Dr. Garber possessed independent knowledge of the different lead sizes that could be used with the Synergy Versitrel System, including leads smaller than the Specify Lead; (4) Dr. Garber elected to implant this device (and lead) in plaintiff; and (5) Dr. Garber has used the Specify Lead in the cervical spine of five additional patients after plaintiff's failed surgery. *See Def.'s Mot. Summ. J. re Pltf.'s Lack of Evidence of Defect And Causation*, pp. 15-16.

Plaintiff's only argument to the contrary is that what Dr. Garber knew about the medical risk from the Specify Lead was insufficient – even though she is not a doctor herself and admitted to rendering her opinions about the sufficiency regarding the warnings ***without once reading Dr. Garber's own testimony about his own level of knowledge***. (Doc. 78, Ex. P, (Ruther Depo., 22:21-23:2) (admitting she did not review the deposition).

Clearly, plaintiff has failed to carry her burden of raising a triable issue regarding whether Dr. Garber would have altered his conduct had he been provided warnings about placing the Specify Lead in the cervical spine. To the contrary, the evidence conclusively proves the ***opposite***: As he himself testified, Dr. Garber continued to place the Specify Lead in the cervical spine, even after learning of plaintiff's lawsuit and her theory that there is some higher risk of paralysis from implanting leads in the cervical spine. (Doc. 78, Ex. A, Garber Depo., 100:20-21).

C. Plaintiff's Breach Of Warranty Claims Also Do Not Survive Summary Judgment

Plaintiff's warranty claims also fail. Plaintiff's implied warranty claims fail for the same reasons that her failure to warn claims fail. There are simply no material disputes of

fact demonstrating that the warnings of paralysis conveyed to the learned intermediary were not proper or that the risks were not already known or appreciated by him.

Additionally, the breach of express warranty claims fail because plaintiff has already testified that she relied on her doctors to select the appropriate device and implant it in the appropriate area. (Doc. 78, Ex. X, Tremaine Depo., 97:20-100:19). Plaintiff has not set forth any evidence that she decided to have the Specify Lead implanted into her because of the patient video, or any other alleged express warranty made by Medtronic.

Like the other claims, plaintiff's breach of express and implied warranty claims fail as a matter of law.

IV.
CONCLUSION

For the above reasons, none of plaintiff's causes of action survive summary judgment, or in the alternative, summary adjudication. Plaintiff sets forth no evidence demonstrating a dispute of any material fact, and as such, summary judgment on her claims is merited.

MORRIS PICKERING & PETERSON

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. Civ. P. 5(b) and Section IV of District of Nevada Electronic Filing Procedures, I certify that I am an employee of Reed Smith LLP; that the following documents were served via electronic service: **MEDTRONIC, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT REGARDING PLAINTIFF'S LACK OF EVIDENCE OF DEFECT AND CAUSATION.**

TO:

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Dated this 30th day of May 2008.

/s/ Veronica Barreto
Veronica Barreto